UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX LABORATORY
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DEC 20 2017

Ms. Christine Sotelo, Chief
Environmental Laboratory Accreditation Program
Division of Drinking Water
California Water Boards
1001 I Street
Sacramento, CA 95814

Dear Ms. Sotelo:

On November 15, 2017, EPA Region IX Laboratory Certification Officers Jack Berges, Shannon Behmke, Andrew Lincoff, Cynthia Williams, and Amy Wagner conducted an overview of California's Drinking Water Laboratory Certification Program. The overview included discussions with you, Supervisors Maryam Khosravifard, Maria Freedman, and Dr. Christpher Ryan, QA Officer Jacob Oaxaca, and Staff Services Analyst, Katelyn McCarthy. The program overview is a Safe Drinking Water Act requirement for the State to maintain primacy.

We wish to congratulate your staff for their accomplishments in the Laboratory Certification Program. I am enclosing my staff's report on the status of your program. We are pleased the program continues to improve in its efforts to establish high standards for in-state and out-of-state environmental laboratories applying for drinking water certification.

Sincerely,

Peter Husby
Laboratory Director

Enclosure

OVERVIEW OF

STATE OF CALIFORNIA

DRINKING WATER LABORATORY CERTIFICATION PROGRAM

December 12, 2017

CONDUCTED BY

Shannon Behmke
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U.S. EPA REGION IX
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INTRODUCTION

On November 15, 2017, Jack Berges, Andrew Lincoff, Amy Wagner, Shannon Behmke, and Cynthia Williams conducted an overview of the State of California Water Resources Control Board's Environmental Laboratory Accreditation Program (ELAP) for drinking water. The purpose of the overview is to ensure that the State's delegated laboratory certification program is in compliance with USEPA regulations promulgated under the Safe Drinking Water Act at 40 CFR 141. The overview was conducted according to the procedures set forth in USEPA's Manual for the Certification of Laboratories Analyzing Drinking Water - Fifth Edition. The overview consisted of discussions with ELAP Manager, Christine Sotelo, and Sacramento program managers and staff, Katelyn McCarthy, Maria Friedman, Chris Ryan, Maryam Khosravifard, and Jacob Oaxaca. After the on-site review of files on November 15, 2017, Laboratory Certification Officers (LCOs) contacted by phone or email were Frank Riley from the Sacramento office and Karen Lee from the Richmond office. The USEPA LCO team also reviewed Quality Assurance documents, ELAP's contractor NV5 Assessor Training Contract documents and assessor training materials, and electronic files for 19 laboratory certifications conducted by ELAP in the past year.

PROGRAM OVERVIEW

Organization/Program Scope and Responsibilities

As of November 8, 2017, CA ELAP issued licenses to 279 drinking water laboratories for chemistry, 307 for microbiology, and 17 for radiochemistry. Of these, 333 are in-state and 40 are out-of-state. California ELAP's policy is that drinking water laboratories are inspected once every three years, meeting USEPA's guidance for onsite visits. However, 70 drinking water laboratories have not been assessed within three years as of December 4, 2017. The drinking water certifications are part of ELAP's larger program which also includes environmental lab licenses for wastewater and hazardous waste.

The California ELAP program transitioned from the California Department of Public Health (CDPH) to the California State Water Resources Control Board in 2014. The State Water Board Division of Drinking Water consists of three branches, with Laboratory Certification Officers in the Northern California Field Operations Branch, Southern California Field Operations Branch, and Program Management Branch. One staff change since 2016 was the addition of Laboratory Certification Officer of microbiology, *Cryptosporidium*, and chemistry, Maria Friedman, who is the supervisor in the Glendale Office.

ELAP withdrew from The NELAC Institute (TNI) as an accrediting body in 2014 but now follows the TNI 2016 standard with modifications. The ELAP program does not plan to seek TNI recognition during their transitional period, but ELAP onsite assessments will begin to

provide laboratories feedback on readiness for meeting the TNI standard (2016) to prepare them for future implementation.

Staffing and Resources

ELAP continues to increase support for laboratory accreditation operations and implemented many reforms outlined in their workplan in addition to recommendations from USEPA and the independent Expert Review Panel. Staff and management training has shown improvement. Several ELAP staff (supervisors and laboratory certification officers) audited or passed USEPA's Laboratory Certification Officer (LCO) microbiology or chemistry training course in Richmond, California in June 2017. NV5/Dade Moeller was awarded ELAP's Assessor Training Contract in June 2017 and the contractor has begun training ELAP assessors. ELAP staff will begin shadowing NV5 assessors while they conduct assessments of drinking water laboratories by geographic location. ELAP currently employs ten LCOs for drinking water, but only six conduct onsite assessments. The third party NV5 assessor contract is designed to absorb 60% of the workload to help clear the program backlog, particularly for laboratories that are near or over the 3-year assessment deadline.

ELAP has begun to increase efficiencies in their accreditation process. Electronic folders are available for laboratories seeking accreditation and generally contain applications, PT results, checklists, assessment reports, and certificates. ELAP's program analyst participated in a Lean Six project and identified strategies to streamline the accreditation process to reduce turnaround times. A decision tree is used to determine who is assigned laboratory assessments, and assessment reviews are conducted by the Laboratory Certification Officer's supervisor. Four full time ELAP staff review Proficiency Testing (PT) results from each applicant laboratory. The PT review is conducted when new and renewal applications are submitted but are not currently reviewed as the study results are available due to the lack of a database to manage the large number of PT results.

ELAP continues to build communication, collaboration, and accountability. ELAP management met with USEPA Region 9 Laboratory Certification Officers twice in 2017 to provide updates on regulations and improvements in the state's laboratory accreditation process and staff and management communicate often with USEPA LCOs. ELAP has undergone a second year of external review under contract with the Southern California Coastal Water Research Project (SCCWRP) Expert Review Panel, which convened a public meeting in January and February 2017, and published a report on program assessment and final recommendations. The panel reported that ELAP has increased credibility with their clients and implemented improvements in the certification process. The Panel recommended continuing to increase resources due to the significant backlog in state certifications, offering more assessor training, and adopting accreditation standards.

Although ELAP withdrew from The NELAC Institute (TNI) as an accrediting body in 2014, the program adopted the TNI 2016 Standard with numerous modifications proposed by the

stakeholder community. ELAP continues to meet with the Environmental Laboratory Technical Advisory Committee (ELTAC), a volunteer committee of laboratories that provide technical feedback to ELAP and serve as a conduit to the laboratory community. ELAP's renewed relationship with state partners has resulted in referrals that led to investigations and enforcement actions by the Program Development, Research and Enforcement Unit. The Regulation team drafted the new set of draft regulations for accreditation of environmental labs and held workshops throughout the state to seek feedback.

Certification Process

CA ELAP's drinking water laboratory certification program is consistent with USEPA's Manual. Laboratories are licensed by method and analyte. Laboratories may be downgraded based upon criteria in Chapter III of the Manual which includes failure to use mandated methods, unacceptable results on Proficiency Testing (PT) samples, failure to notify the State of changes in address or key personnel, and deficiencies found during on-site evaluations. It is recommended that the ELAP Quality Assurance Manual includes a Standard Operating Procedure describing the process for downgrading or revoking certification.

Record Review

The evaluation included a review of a selection of CA ELAP's recent certification records of public and private drinking water laboratories. The following files were audited:

Laboratory	Onsite Inspection Date
Los Angeles County Public Health Laboratory	11/04/16
Western Environmental Testing Laboratory - Las Vegas	N/A – reciprocity
Marin Municipal Water District	10/26/16
Foster Farms	02/16/17
City of Brentwood	06/14/17-06/15/17
Ventura County Waterworks	01/25/17
K Prime	06/16/17
Sonoma County Public Health Laboratory	02/05/17
City of Davis Wastewater Treatment Plant	12/02/17
City of Livermore Water Reclamation Plant	10/28/16
Santa Cruz County – Health Services Agency, Public Health Lab	10/27/16
Eurofins Eaton Analytical, Inc – Monrovia, CA	3/6/17
City of Vacaville Utilities Department Laboratory	10/18/16
South Bay Wastewater Chemistry Laboratory	9/20/16
City of Sacramento, Water Quality Laboratory	4/26/17
Forensic Analytical Laboratories, Inc.	5/17/17
Precision Enviro-Tech	9/1/16
Ceres Analytical Laboratory, Inc.	N/A - Reciprocity
IEH-JL Analytical Services	9/1/16

FINDINGS AND RECOMMENDATIONS

Program Administration

Certification Issuance

Review of the electronic laboratory files revealed issues with the issuance of interim certificates, certificate dating, and documentation of reciprocity certifications.

Interim certifications

ELAP's Interim certification issuance process was inconsistently followed. ELAP's regulations allow an interim certification period of 12 months, and the program has issued 124 interim drinking water certificates from November 1, 2016-November 1, 2017. The file review revealed that some laboratories appeared to have expired certifications since no Interim certification was issued (City of Davis, City of Livermore, Santa Cruz County).

Certification dating

The lab files contain instances where the date that certification was granted or the duration of the certification was incorrect. For Eurofins Monrovia, four certificates were present in the file with differing dates. Also, the laboratory was certified by reciprocity for radiochemistry for a period that exceeded the Oregon primary certification period by one year.

Reciprocity certifications

The ELAP certificates do not differentiate when a laboratory has been granted certification through reciprocity. The Eurofins Monrovia certificate did not indicate that portions of the lab's fields of testing were certified through reciprocity with Oregon. Certificates should clearly state which parameters are granted by ELAP as the primary accrediting body or by another accrediting body.

Onsite Assessment

In the past, USEPA's audit reviews focused on the technical findings made by ELAP auditors. During the previous audit review, ELAP was transitioning to a paperless filing system and Proficiency Testing (PT) results were the only documents consistently available. Therefore, USEPA's audit review focused mainly on Proficiency Testing (PT) results. ELAP now has moved many of its laboratory audit files to a paperless system consisting of electronic folders (i.e., Master file) and the ELAP Tool. The documents in this system contain information from 2015 to present day. USEPA's 2017 audit review focused on the completeness of these files, as well as the technical findings made by ELAP auditors.

The electronic folders were organized by laboratory, and generally contained the laboratory's Quality Assurance Manual, PT results, opening and closing conference checklists, onsite assessment report (OSAR), corrective action report (CAR), important communications between the ELAP auditor and lab personnel, and laboratory certifications with accredited fields

of testing (FOTs). Documentation within each folder was usually comprehensive and easily available to program auditors. This allowed USEPA to adequately audit the ELAP program against the Quality Control (QC) criteria in USEPA's Drinking Water Certification Manual. There were, however, some inconsistencies in file structure and contents. For example, some laboratory files had multiple PT folders. Some PT folders contained PTs from a single year, while others contained multiple years with over 100 PT reports. This made it difficult to determine whether the lab had acceptable results in the past year. Furthermore, some labs had multiple main folders in the Master file, which, in one case, contained documents from more than one laboratory. It would be useful to develop a single file structure and have a procedure for filing QC.

From audit to corrective action to certification issuance, auditors effectively communicated with laboratory personnel and efficiently saw the laboratories through the process. OSARs were completed within two to 60 days of onsite assessments. One exception was the City of Brentwood, which had an onsite assessment and was issued a full certification but has no OSAR on file.

Microbiology audit files contained a checklist for each onsite assessment. These checklists were comprehensive and well-organized. Nearly all microbiology checklists were thorough and complete, allowing USEPA auditors to adequately review technical findings made by ELAP auditors. Although a few checklists were not complete, overall, auditors were much improved from last year. This will only be enhanced by additional training and shadowing.

Technical Findings

The technical staff has showed increased documentation in their use of checklists as well as correspondence of findings. ELAP has recently revised the microbiology checklist, which is very comprehensive and provides consistency among auditors conducting microbiology laboratory evaluations.

However, a few exceptions were found in the file review. If media is not prepared in the laboratory, LCOs should still check laboratory autoclave records for sterilization and disposal of microbiological wastes. Some checklists were incomplete (e.g., Santa Cruz County Public Health for Colisure) and did not indicate that critical elements were covered in the laboratory evaluation (e.g., City of Livermore for temperature devices and incubator). A more complete review of the methods and documentation of the audit are suggested for the ELAP auditor associated with these laboratory files. This is to ensure that all auditors are consistent and thorough in their inspections. Additionally, the ELAP microbiology checklist should include a sterility check for growth at 48 hours in sample containers consistent with the Manual section 4.2.

In the Eurofins lab report for microbiology, the auditor stated that the pH meter used to check media was only calibrated at 7 and 10, however, a comment in the report stated, "It is noted that all laboratory prepared media fall within pH 7 and 10 bracket." This is not correct. The lab is certified for Standard Methods 9221 B and E which use LTB and EC media. The

expected pH of these media are 6.8 and 6.9, respectively, so the pH meter should be calibrated at pH 4 as well.

For Forensics Analytical, PT report WS-237 shows results for total coliforms, fecal coliforms and E.coli from a single sample set run using Colilert. This is not acceptable. Colilert cannot be used for fecal coliform analysis in drinking water. While there is an alternative Clean Water Act procedure using Colilert at elevated temperature to measure fecal coliforms only, Colilert cannot simultaneously measure all three. The lab should be informed that they should not report results for fecal coliforms when using Colilert. In addition, the lab erroneously reported the results as CFU/100 mL instead of MPN/100 mL.

Proficiency Testing (PT) Evaluation

The PT Review team has made considerable progress since last year's USEPA Program Overview. Based on last year's report recommendations:

- PT results are listed in the ELAP Access Tool and accessible electronically in the laboratory's master files.
- If a lab fails a PT, the PT Review Team contacts the laboratory for a re-analysis or an option to withdraw certification for the FOT parameter. This ensures that the LCO does not certify for a FOT that the laboratory has not successfully submitted acceptable results.
- ELAP has improved evidence in files that certification for laboratories that fail or do not submit PTs are denied certification for that FOT.
- For new and renewal applications, ELAP requires laboratories to submit copies of the PT reports for the FOT for which they request certification.
- ELAP has updated SOPs to reflect current practices with PTs.

The following improvements should be made to the PT Program:

- PT records should be listed by year in the laboratories electronic master files.
    - PT review by the PT team were documented in ELAP Tool, but not all PT records were found in the electronic master files. From our file review, almost 50% of the files did not contain complete sets of annual PT results for the proper FOTs. One example from Eurofins Eaton Analytical Inc., revealed no PT records to indicate that Eurofins passed a PT after failing for one FOT. However, a certificate was issued to the laboratory. It is possible the PT group completed the review but it is not clear from reviewing the master files.
- PT records should be reviewed annually.
    - USEPA's Drinking Water Laboratory Certification Manual states that labs must submit acceptable PT results annually for Chemistry and USEPA has always recommended the same for Microbiology. Due to an onerous workload and limited staff resources, ELAP only reviews labs' PTs when

an application is submitted (every 2 years), prior to auditing for initial licensing and annual relicensing. This is a digression in PT oversight. From 2016-2017, the PT Review team reviewed PT records annually. USEPA noted that even that practice would not address a PT failure until months after submittal.

- Create a PT assessment database (high priority).
    - Currently, the decision to either develop an in-house program or purchase a program off-the-shelf to evaluate PT results is being assessed by the State Water Board's Information Technology group.
    - USEPA strongly urges ELAP to devote significant resources and efforts to creating or purchasing a PT evaluation database. This would significantly streamline the PT review process allowing for real-time PT data review.

Conclusions

ELAP has made significant progress with onsite assessments, electronic filing, technical training of LCOs, and communication with its customers. The USEPA team believes that training from the third party NV5/Dade Moeller contract will continue to improve consistency and reduce the backlog in LCO onsite evaluations. Main areas of concern include the strong need for a PT database and revisions in the certificate issuance process. Specifically, PTs must be reviewed annually (preferably in real-time), the issuance of interim certifications due to backlog of onsite evaluations needs to be decreased, and primary and secondary certificates for reciprocity need to be specified on the certificates. If ELAP is the primary certification agency for some FOTs, but the secondary for others, that must be readily apparent.